SURGICAL INSTRUMENTS

S.I.N. Surgical Drivers

The S.I.N. Surgical Drivers are intended for specialized procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRODUCT DESCRIPTION

S.I.N. Surgical Drivers are produced in stainless steel, at one it has a fitting for contra-angle (active device) and at the other end there is a specific active tip for fitting with implants, components or screws.

INDICATIONS OF USE

S.I.N. Surgical Drivers are used to assist in the surgical procedure or in the fixation/removal of implants and components.

PURPOSE AND OPERATION PRINCIPLE

The finality is to enable the installation of dental implants, through the aid in the surgical procedure, in the transport or fixation of the implant or component. All driver function based on mechanical principles of force transmission, for the activation of secondary elements.

HOW TO USE THE INSTRUMENT

S.I.N. Surgical Drivers must be selected according to the specific fit of the implant and/or component and must be connected to the contra-angle and motor for use. It is necessary to adjust the rotation and torque of the motor according to the recommendation of the implant/component to be installed.

⚠ ATTENTION

S.I.N. Surgical Drivers are intended for specialized procedures, which must be performed by qualified professionals in implantology. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTIONS

S.I.N. Surgical Drivers should be selected according to the implant/component installation recommendations. Use of excessive force or disengagement between parts can damage the product. Before each procedure, ensure the perfect fit between the parts and the condition of the instruments, always respecting their useful life. It is necessary to replace the instruments in case of damage, erased markings, compromised sharpening, deformations and wear.

RECOMMENDATIONS

The product should be used only by qualified dental professionals who already have all the scientific information necessary for the correct use of the product. Always perform cleaning and sterilization as recommended before the surgical procedure. It is necessary to check the functionality, fitting capacity or accuracy of these products after each procedure and if there is natural wear and tear generated by use, they must be replaced and discarded.

CONTRAINDICATION

Use for purposes other than the installation or removal of implants and prosthetic components.

SIDE EFFECTS

Failure may occur due to factors intrinsic to the surgical procedure, such as the local and health conditions of the implanted individual and the skill and knowledge of the professional who practices it.

WARNING

Do not use the instrument if you notice cracks, wear or spots of oxidation/corrosion. This may cause problems in the operation of the instruments. All items may exhibit natural wear and tear and should be replaced whenever the professional identifies loss of fit or accuracy of these products as they may interfere with the result of the work.

TRACEABILITY

All S.I.N. products have sequential batches that allow traceability, thus promoting greater safety for professionals skilled for the procedure. Through this lot number it is possible to know all product history from the manufacturing process to the time of distribution.

STORAGE

S.I.N. Surgical Drivers should be stored in a cool dry place at a temperature of 15°C to 25°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

Once sterilized, the instruments should be handled in a sterile environment by properly attired professionals and in appropriate clothing at the time of surgery to install implants. Scratches or notches of the instruments should be avoided as such factors can increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

TRANSPORTATION

S.I.N. Surgical Drivers must be transported adequately to avoid falling and stored at a maximum temperature of 25ºC, protected from heat and moisture. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for dental use. Reprocessing is allowed. Refer to the cleaning and sterilization conditions contained in this instruction for use. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Prepare the enzymatic detergent according to the detergent manufacturer's instructions.
2. Immerse all parts of the product into the prepared detergent solution and leave for 5 minutes. Then, using a soft bristle brush, scrub the parts for at least 2 minutes until you completely remove organic matter from the products.
3. Remove the parts from the detergent solution and rinse with tap water for 1 minute until the residue is completely removed. Repeat the rinse two more times.
4. Visually inspect each part to check for process residues or organic residues from the use of the product.
5. If residue in detect in the product, repeat the cleaning process until the residue is completely removed.
6. Dry with soft, clean, dry cloth or disposable paper.
7. Proceed with the sterilization process.

RECOMMENDATIONS

a. Wear appropriate clothing (gloves, masks, glasses, hats, etc.)
b. Begin cleaning immediately after surgical use.
c. Never let the instrument dry containing organic residues after surgical use.
d. Never let the instrument dry naturally after cleaning.

e. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide or alcohol to clean or rinse surgical instruments and Kit trays.
f. Never use steel wool or sponges or abrasive products, so that the instruments are not damaged.
g. Do not accumulate instruments in large quantities on top of each other to avoid deformation of smaller and delicate pieces.

STERILIZATION

Reusable product and provided non-sterile. It must be clean and sterilized in autoclave before use.

1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed with a sterilizable steam wrap.
3. Steam sterilizes in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. Never stack objects or other cases.

RECOMMENDATIONS

a. Sterilize the products on the same day or one day earlier the procedure.
b. Chemical sterilization is not recommended, since some products may cause discoloration and damage to the case.
c. Do not use temperature higher than 60°C to drying process.
d. Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. Implant System.

LIFETIME

It is estimated that the instruments that are not articulated, with connection to equipment, non-cutting, can be submitted to 250 uses. It is necessary to check the functionality, fitting capacity or accuracy of these products after each procedure and if there is natural wear caused by use, they must be replaced and discarded.

	NÃO ESTÉRIL	NON-ESTERILE	NON STÉRILE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTER LE MODE D'EMPLOI
	MARCAÇÃO CE	CE MARK	CE MARQUE
	MANTENHA SECO	KEEP DRY	GARDER AU SEC
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	TENIR À L'ABRI DE LA LUMIÈRE DU SOLEIL
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NE PAS UTILISER SI L'EMBALLAGE EST ENDOMMAGÉ
	ATENÇÃO	CAUTION	ATTENTION
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRÉSENTANT AUTORISÉ DANS LA COMMUNAUTÉ EUROPÉENNE
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LIMITE DE TEMPÉRATURE
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR OU POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO.	CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER.	ATTENTION: LES LOIS FÉDÉRALES (AMÉRICAINES) LIMITENT LA VENTE DE CET APPAREIL PAR OU SUR ORDRE D'UN PROFESSIONNEL DE LA SANTÉ AGRÉÉ.
	FABRICANTE	MANUFACTURER	FABRICANT
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	DATE DE FABRICATION
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CODE DE RÉFÉRENCE
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIF MÉDICAL
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICATEUR UNIQUE DE L'APPAREIL
	IMPORTADOR	IMPORTER	IMPORTATEUR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUTEUR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAYS DE FABRICATION
	LOTE	BATCH CODE	CODE DE LOT
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALLAGE RECYCLABLE
DESCRIPTION ON THE LABEL	CONTÉM: 1 UNIDADE	CONTENT: 1 UNIT	CONTENU: 1 UNITÉ
DESCRIPTION ON THE LABEL	PRODUTO NÃO ESTÉRIL	NON STERILE PRODUCT	PRODUIT NON STÉRILE

MANUFACTURER
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SYSTEM
S.I.N. Surgical Drivers

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